EXHIBIT H

PARRISH LAW OFFICES

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March 27, 2019

VIA PRIORITY MAIL

DHHS – OMHA
Centralized Docketing
Attn: Beneficiary Mail Stop
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

BENEFICIARY APPEAL

RE: Request for ALJ Hearing
Beneficiary: Anniken Prosser
W2973 Farmstead Dr.
Appleton, WI 54915
Dates of Service: 8/16/2018; 9/16/2018; 10/16/2018
HICN: 4R87U71QM75
Medicare Appeal No: 1-8285761650
Date of QIC Decision: March 19, 2019
Device: Tumor Treatment Field Therapy (E0766)
Supplier: Novocure, Inc.
Our Ref: 19-53

Dear Claims Coordinator:

As an authorized representative of the above-captioned Medicare beneficiary, Anniken Prosser, I hereby appeal to an Administrative Law Judge the above-captioned decision rendered by the Qualified Independent Contractor ("QIC") C2C Innovative Solutions, Inc. for the claims submitted for tumor treatment field therapy ("TTFT") for a glioblastoma. **If possible, pursuant to 42 C.F.R. § 405.1006(e), Appellant requests that the immediate case be consolidated with another case pending before Judge Figueroa for the same beneficiary for the same device (ALJ Appeal No. 1-8380637906) in the interest of OMHA efficiency.**

The QIC rendered nonsensical denials, stating "the medical documentation of the efficacy of this device is not within the usual scope and breath (sic) of current medical literature with peer acknowledgement and review." The QIC also asserts that although the DMACs acknowledged a valid reconsideration request was filed, LCD L34823 remains applicable until the DMACs retire it or issue a new LCD.

Ms. Prosser was diagnosed with a glioblastoma in 2016. She had surgery and was treated with radiation and chemotherapy. Her clinician also prescribed TTFT. TTFT disrupts and corrupts the division of cancer cells and leads to the death of such cells. In 2011 and 2015, the FDA approved, through its more rigorous review process, a device to deliver TTFT, finding it to be safe and effective for the treatment of glioblastomas. During the clinical trial for newly diagnosed glioblastomas the TTFT results were so compelling that at the interim analysis, the Data Safety Monitoring Board recommended that those not receiving TTFT be able to cross over to receive the treatment. The FDA agreed. Notably, the DME MAC medical directors have asserted that they do not interpret the LCD as applying to cases of newly diagnosed glioblastoma. Please see Att. C to the reconsideration request.

The published, peer-reviewed literature shows the improved clinical survival and the progression-free survival of patients who receive TTFT for their glioblastoma. TTFT for glioblastoma is included in the National Comprehensive Cancer Network ("NCCN") guidelines and is considered the standard of care for newly diagnosed glioblastoma. Hundreds of treating physicians, in all 50 states, have prescribed TTFT. TTFT is covered by all the large national payers. Medicare has paid for numerous claims for medically indistinguishable beneficiaries.

The QIC's determination is nonsensical. The seminal articles showing the effectiveness of the treatment/device were published in JAMA, one of the most prestigious journals in the country based on "impact factor." JAMA is a peer-reviewed publication, thus the assertion that the documentation lacks review is belied by the evidence. Multiple peer-reviewed articles show the effectiveness of the device, to the QIC's comment regarding scope and breadth. The inclusion of TTFT in the NCCN guidelines is "peer acknowledgment and review."

With respect to the LCD, the enclosed documents show that the LCD has not kept pace with the current peer-reviewed literature, regulatory status, consensus of experts, scientific evidence or adoption by the relevant medical community. As noted in the QIC decision, an LCD which conflicts with the standard of care must be "based on sufficient evidence to convincingly refute evidence presented in support of coverage." No such evidence exists. Indeed, the list of documents supporting the LCD shows that the DMACs have not considered any of the regulatory approvals, peer-reviewed literature, or consensus statements that have issued since 2014. Please see attached CMS Exhibit List from LCD Record.

On March 6, 2019, the Carrier Advisory Committee recommended Medicare coverage of TTFT. The experts found that the peer-reviewed literature showed the treatment was safe and effective. The experts did not find that the studies were limited in number or biased. Most of the published clinical research on a medical intervention is sponsored in the United States. Indeed, Medicare often requires industry to sponsor certain studies as a condition of coverage. A cursory review of the literature supporting most LCDs shows that they are sponsored studies. Industry sponsorship does not make a peer-reviewed study, written by academic authors, "not non-biased" such that Medicare should not consider it.

If you have any questions or the items appended to the underlying reconsideration requests were not forwarded to your offices by the QIC, please do not hesitate to contact us at (412) 561-6250.

Yours very truly,

Debra M. Parrish on behalf of
Ms. Anniken Prosser

Enclosures:

Attachment A: Appointment of Representative Form
Attachment B: Certificate of Service
Attachment C: Exhibit List from LCD Record

cc: Ms. Anniken Prosser

Novocure, Inc., c/o Justin Kelly
195 Commerce Way
Portsmouth, NH 03801
(603-501-4299)

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April 10, 2019

VIA PRIORITY MAIL

Judge Kimberley Woodyard
Office of Medicare Hearings and Appeals
Kansas City Field Office
601 E. 12th St., Suite 221
Kansas City, MO 64106

RE: Prehearing Brief
ALJ Appeal No. 1-8416188648
Appellant/Beneficiary: A. Prosser
Service: E0766
Dates of Services: 8/16/18, 9/16/18, 10/16/18
Hearing Date: TBD
Our Ref. No.: 19-53

Dear Judge Woodyard:

In anticipation of the scheduling of the above-captioned case, please find attached a prehearing brief to aid in your analysis. We have compiled (1) additional studies from 2018 and 2019 and (2) textbook chapters from medical textbooks since the filing of the reconsideration request, which are included on the attached CD. The LCD Record Exhibit List detailing the documents considered by the contractor for L34823 is also included.

If you have any questions regarding the foregoing, please do not hesitate to contact me at (412) 561-6250. We appreciate your consideration.

Respectfully submitted,

Debra M. Parrish
Attorney for A. Prosser

Enclosures:

Attachment A: Prehearing Brief
Attachment B: CD containing:
-LCD Record Exhibit List
-TTFT bibliography for GBM & additional peer-reviewed studies from 2018 & 2019 - (aside from those previously submitted with the reconsideration request)
-Medical school textbook excerpts

cc: Ms. A. Prosser